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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/818,534	03/14/97	NELSON W	3922

HM12/0816

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EXAMINER	
HINES, J	
ART UNIT	**PAPER NUMBER**
1645	26

DATE MAILED: 08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/818,534	Nelson et al.
Examiner	**Group Art Unit**
Ja-Na Hines	1645

☒ Responsive to communication(s) filed on *Jun 14, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is clos d** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *2 and 9-12* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *2 and 9-12* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Continued Prosecution Application

1. The request filed on June 14, 2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/818,534 is acceptable and a CPA has been established. An action on the CPA follows.

Drawings

2. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Response to Arguments

3. Applicant's arguments filed June 14, 2000 have been fully considered but they are not persuasive. Claims 2, 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al. (US 4,487,198) in view of Herron et al., is maintained.

Applicants argues that the unexpectedly discovered that irradiating antibody molecules bound to antigens of the microorganisms does not produce resonance Raman spectra which interferes with the resonance Raman spectra of the irradiated microorganisms. However, applicants mere statement of unexpected results is insufficient. Applicant has not provided data which states this method has produced unexpected results. Applicant argues that Herron et al.,

does not teach that changes in the immobilization produce would produce resonance spectra that may be obscured therefore changes in immobilization procedures would not have been obvious to one of skill in the art, however Nelson et al., teaches that fluorescence produced at energies below 270nm by the organisms and associated media does not interfere with the resonance Raman signal since a "window" between the exciting frequency and the onset of fluorescence allows the sensitive detection of resonance enhanced Raman scattered light (col. 5 lines 27-34). No more then routine skill have been required at the time of applicants' invention to have used capture molecules like antibodies immobilized to a solid phase which specifically bind in antibody-antigen complex where the antigen or analyte is a microorganism as taught by Herron et al., in conjunction with a method for detecting the presence of a specific microorganism in a sample without interference to the energy spectra as taught by Nelson et al., because Herron et al., teaches immobilizing bacteria using antibodies is well known in the art as a method of immobilization.

Therefore, there would have been a reasonable expectation of success to use a well known method such as using capture molecules like antibodies immobilized to a solid phase which specifically bind in antibody-antigen complex where the antigen or analyte is a microorganism as taught by Herron et al., in conjunction with a method for detecting the presence of a specific microorganism in a sample as taught by Nelson et al. One would expect reasonable success by employing the effective range of use between 190-260nm which encompasses the range of the instant application and evidenced by the narrowing of the range to

242 since five different types of bacteria are excited at 242 nm as taught by Nelson et al. Further, Nelson et al., teaches that rapid analysis is possible using resonance Raman spectra because it exhibits differences in the composition in the nucleic acids which are major contributors to the spectra reported.

4. Claims 2 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chadha et al., in view of Herron et al., is maintained.

In response to applicant's argument that unexpected results were discovered by irradiating antibody molecules bound to antigens of the microorganisms does not produce resonance Raman spectra which interferes with the resonance Raman spectra of the irradiated microorganisms. However, applicants mere statement of unexpected results is insufficient. No more then routine skill is required to substitute biospecific antibodies for the disclosed polylysine, because biospecific antibodies are conventionally used to immobilize bacteria analytes for assay. Further, changes in concentrations or the amount of antibody for an process known in the art does not impart patentability. Chadha et al., teaches that resonance Raman spectra of a number of bacteria and bacterial spores, excited at 200-257nm have been reported.."(page 3089 para. 2). "With 242, 252, 257nm excitation, vibrational modes of various nucleosides, nucleic acids, quinones, and calcium dipicolinate are selectively excited.."(page 3089 para. 2). "Nucleic acids have a prominent absorption band around 260 nm, consequently it is not surprising Raman spectra with 257 nm excitation would contain several strong resonance enhanced vibrational

modes due to nucleic acids." (page 3092 para. 3). Further Chadha et al., teaches the benefits of washing cells and for using nucleic acids as markers because they show strong resonance enhanced vibrational modes and provided better signals over the interference in Raman spectroscopy. The instant application states a wavelength range between 242-257nm, however Chadha et al., teaches the benefits for using 242nm (because it promises better signal to noise even if Raman cross sections are lower) and 257nm (because it would contain several strong resonance enhanced vibrational modes due to nucleic acids) and that the wavelengths of 242, 252, 257nm are selectively excited for the vibrational modes of various nucleosides and nucleic acids. Therefore, Chadha et al., does not teach away from modifying the mode of immobilization.

accordingly there would have been a reasonable expectation of success for one skilled in the art to modify the method and system of Chadha et al., by substituting the immobilization of antibody to a solid phase because the specificity of antibodies are conventionally used to bind and immobilize bacterial antigens for an assay as taught by Herron et al., without obscuring the Raman spectra energy.

5. Applicant submitted a paper authored by Wu et al., under 37 CFR 1.132 filed June 14, 2000. However the Declaration is still insufficient to overcome the rejection of claims 2 and 9-12 based upon Chadha et al., or Nelson et al., in view of Herron et al., because it refers to a peer reviewed paper with no date. The document does not state and/or show data that other method of immobilization obscure Raman spectra energy and that unexpected results were achieved by the

immobilization procedures of the instant application. Further, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MEP. § 716. Therefore, the Wu et al., paper is not persuasive.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

August 8, 2000

JENNIFER GRASER
PATENT EXAMINER